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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,225	11/07/2001	Giampiero Valleta	C36226/127436	5568

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Bryan Cave
245 Park Avenue
New York, NY 10167

EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,225

Applicant(s)

VALLETA, GIAMPIERO

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-11, 16-19 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 11, 16-19, 22-24, 29-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 25-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election acknowledged

1. Applicants' affirmation on the election of Group II, claims 8-11 and 25-28, and pruritus as the elected species is acknowledged. Applicant's election is made with traverse. As stated in the previous office action, because the instant application is a national stage application of a PCT filing, the support for the restriction/election requirement is lack of unity between the each groups II-III. The special technical feature which is referred to Annex B of Appendix A1 of the MPEP(Administrative Instructions under the PCT, "Unity of Invention"). The express "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art."(Rule 13.2). The question of unity of invention has been reconsidered retroactively by the examiner and the examiner concluded that the groups I-III do not share "special technical feature" which support the unity of invention. The technical feature(i.e. a combination of nicotinic acid and riboflavine) is not considered to be a special technical feature in this case as evidenced by Patrick(US5496827) or Blass(US5053396) because each patentee teach the claimed technical feature and thus, the unity of invention is lacking. A review of these references makes clear that the claimed species is not novel over the prior art (the instantly claimed compounds). Furthermore, these references appear to demonstrate that the claimed combination does not define a contribution which each of the inventions, considered as a whole, makes over the prior art. The elected species(i.e. pruritus) is requiring therapeutically different treatment that other non-infective, non-neoplastic, non-rheumatic disorders involving itching and/or inflammation(e.g. asthma). As mentioned earlier, each species lack unity where the treatment can be achieved by materially different therapeutic modalities, the election requirement deems to be proper. Accordingly, the prior art of the record supports restriction of the claimed subject matter and claimed species. Thus, the restriction/election deems to be proper and made Final.

Status of Application

1. The claims 1-4, 8-11, 16-19 and 22-30 are pending. Upon entering the election, the elected claims 8-10 and 25-28 have been examined only to the extent that they read on use of the elected species in the claimed method. All remaining (or portions thereof) not drawn to the elected species are withdrawn from further consideration as being non-elected. The following rejections are made.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating and/or for the prophylaxis of pruritus, does not reasonably provide enablement for the prophylaxis of all the disorders which is non-infective, non-neoplastic, non-rheumatic disorders involving itching and /or inflammation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl) at 547 the court recited eight factors:

- 1) the quality of experimentation necessary,
- 2) the amount of direction or guidance provided,

- 3) the presence of absence of working example,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicants fails to provide information allowing the skilled artisan to ascertain “the scope of all the possible disorders that are non-infective, non-neoplastic, non-rheumatic disorders but involve itching and /or inflammation and the treatment of the said disorder using the claimed combination of nicotinic acid and riboflavin”. In the instant case, only a limited number of examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of diseases required. The instant claims read on all “the disorders complicated by itching and/or inflammation”, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Applicant fails to set forth the criteria Therefore, based on the unpredictable nature of the invention and state of the prior art, the lack of guidance and working examples, and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

However, pruritus has been elected for the examination purpose, the said 112 rejection will be addressed again when the prosecution is extended to for reviewing

other non-elected species. Or deleting those said non-elected species from the instant claims would expedite the prosecution.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "(i.e.)" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation "pruritus associated with renal insufficiency or failure", and the claim also recites(i.e. uremic pruritus) which is the narrower statement of the range/limitation. claim 10 recites the broad recitation

"itching of aged skin", and the claim also recites(i.e. senile pruritus) which is the narrower statement of the range/limitation. Appropriate correction is required.

Allowable Subject Matter

5. Claims 26-27 are allowable.
6. The following is a statement of reasons for the indication of allowable subject matter: US 5496827 teaches a combination of methyl nicotinate and riboflavin. The ration of riboflavin: methyl nicotinate is 3:1 for the treatment of dermatitis. The claimed subject matter utilizing specific ration which could bring unexpected improvement on relieving itching symptoms are not taught in the prior art of the record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-10 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scivoletto (US6248763) in view of Patrick (US 5496827) and .

The claims are drawn to a method for treating prutitus(itching) using a combination of nicotinic acid and riboflavin.

Scivoletto(US'763) teaches a pharmaceutical composition used in the treatment of itching from insect bites, bee stings or fungi(including athletes foot and jock itch), and

itching associated with other skin disorders such as atopic dermatitis, seborrheic dermatitis, rash, acne, psoriasis, etc(see abstract and claims).

It is noted that pruritus that is a medical term for itching.

Applicant's claims differ from US'763 because they require a combination with riboflavin as second active agent.

Patrick(US'827) teaches a composition comprising an effective amount of nicotinic acid(i.e. methyl nicotinate) for treating dermatitis, acne or eczema, see abstract and column 5, lines 5-51. It further teaches addition of riboflavin into methyl nicotinate composition could be beneficially enhanced the therapeutic efficacy of said nicotinic acid, see column 3, lines 10-15.

Kasler et al(US'844 hereafter) teaches a riboflavin is essential for itching and inflammation in the skin, see column 1, lines 10-15

At the time of the invention was made, when Scivoletto(US'763) is modified with latter references(US'827) and ((US'844), it would have been obvious to treat itching(pruritus) with a combination composition of nicotinic acid (or its derivative such as methyl nicotinate) and riboflavin because the treatment can be advantageously benefitted by the said combination than a treatment with single agent as suggested by these references especially when it is taken together. Above references in combination make clear that riboflavin and nicotines(nicotinic acid derivatives) have been individually used for the treatment of itching. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The

combination of active ingredient with the same character is merely the additive effect of each individual component. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

As to the claims 9-10, 25 and 28, app the claims are properly included in this rejection because litching taught these references are not connected with primary organic affects and thus, it meets the claims and also minor variations including routes of administration are well within the skilled level of the artisan. Nicotinic acid(Vit. B3) and riboflavin(Vit. B2) are well known vitamins and the oral or parenteral administration is already well known.

One would have been motivated to do so because combination could maximize the therapeutic efficacy wherein the lower therapeutic dose for each ingredient and thereby reduces unwanted side effect which is associated with high doses of active agent and also reduces manufacturing cost. One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extend the usage of application to various areas of body because relieving itching symptoms regardless of the body parts can be achieved same because underlying mechanisms (e.g. histamine, cytokine) for the itching symptoms are very same. Each reference is particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

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8. Claims 26-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Primary Patent Examiner
Art unit 1614